

Claim Amendments

Claims 1 to 122 *CANCELLED*

Claim 123 *(Currently amended)* A concentrated liquid hormone composition for use in compounding a pharmaceutical product for topically delivering one or more steroid hormones to a subject in need of hormone replacement therapy, ~~comprising:~~
a) ~~one or more naturally occurring steroid hormone(s); and~~
b) ~~a combination of penetration enhancing solvents that promotes delivery of the steroid hormone(s) through the dermis following topical administration;~~
~~with the proviso that the composition is essentially free of water; and~~
~~wherein the combination of penetration enhancing solvents comprises~~
comprising one or more naturally occurring steroid hormone(s) dissolved in a solvent mixture consisting of ethoxy diglycol and propylene glycol.

Claim 124 *CANCELLED*

Claim 125 *(Currently amended)* The concentrated liquid hormone composition of claim 123, wherein the ~~solvents in the composition consist essentially of~~ solvent mixture is about 50% ethoxy diglycol and about 50% propylene glycol (vol/vol).

Claim 126 *(Currently amended)* The concentrated liquid hormone composition of claim 123, comprising one or more estrogen(s) at a total concentration of at least 40 mg per gram.

Claim 127 *(Currently amended)* The concentrated liquid hormone composition of claim 126, wherein said estrogen(s) are selected from estriol, estradiol, and estrone.

- Claim 128 *(Currently amended)* The concentrated liquid hormone composition of claim 123, comprising at least one androgen at a concentration of at least 150 mg per gram.
- Claim 129 *(Currently amended)* The concentrated liquid hormone composition of claim 128, wherein said androgen is selected from testosterone and dehydroepiandrosterone (DHEA).
- Claim 130 *(Currently amended)* The concentrated liquid hormone composition of claim 123, comprising at least one progestagen at a concentration of at least 200 mg per gram.
- Claim 131 *(Currently amended)* The concentrated liquid hormone composition of claim 130, wherein said progestagen is selected from progesterone and pregnenolone.
- Claim 132 *(Currently amended)* A concentrated liquid hormone composition for use in compounding a pharmaceutical product for delivering hormones to a subject in need of hormone replacement therapy, comprising a plurality of different naturally occurring estrogens dissolved ~~or suspended in one or more solvent(s) or wetting agent~~ in a solvent mixture of ethoxy diglycol and propylene glycol at a total concentration of least 6 mg of estrogens per gram.
- Claim 133 *CANCELLED*
- Claim 134 *(Previously presented)* The concentrated composition of claim 132, wherein the composition comprises about 40 mg of estrogens per gram.
- Claim 135 *(Currently amended)* The concentrated composition of claim 132, wherein the estrogens are ~~estriol and estradiol, and optionally~~ estriol, estradiol, and estrone.
- Claim 136 *CANCELLED.*

Claim 137 (*Previously presented*) The concentrated composition of claim 135, wherein the ratio of estriol, estradiol, and estrone by weight is 8:1:1, 5:4:1, 6:3:1, or 7:2:1.

Claim 138 *CANCELLED*.

Claim 139 (*Withdrawn-Currently amended*) A method for preparing the concentrated composition of any of ~~claims 123-138~~ claims 123, 125 to 132, 134, 135, and 137, comprising:
a) combining said steroid hormone(s) with said solvent(s) ~~or wetting agent~~; and
b) processing said combination in an ointment mill or homogenizer to decrease particle size of said hormone(s) in the combination.

Claim 140 (*Currently amended*) A plurality of concentrated hormone compositions according to any of ~~claims 123-138~~ claims 123, 125 to 132, 134, 135, and 137.

Claims 141 to 160 *CANCELLED*

Claim 161 (*Previously presented*) The compounding method of ~~claim 160~~ claim 164, wherein the needs of ~~each consumer are~~ the consumer is ascertained by way of a prescription from a doctor for replacement of particular hormone(s) each in a particular amount.

Claims 162 to 163 *CANCELLED*

Claim 164 (*Currently amended*) ~~The compounding method of claim 160, wherein the penetration enhancing solvents are~~
A method for compounding a pharmaceutical product for administering one or more hormones to a consumer in need of hormone replacement therapy, whereby the product is custom tailored for each individual consumer, the method comprising:

a) obtaining a plurality of concentrated liquid reagent compositions, at least one of which comprises one or more steroid hormone(s) dissolved in ethoxy diglycol and propylene glycol ;
b) ascertaining the needs of an individual consumer; and
c) compounding a plurality of said concentrated reagent composition(s) into said pharmaceutical product at a ratio that is custom tailored to the individual needs of said consumer, wherein the final concentration of each of said steroid hormone(s) in the pharmaceutical product is sufficient to be therapeutically effective for the consumer in accordance with their needs.

Claim 165 *(Currently amended)* The compounding method of ~~claim 160~~ claim 164, wherein at least one of the concentrated reagent compositions contains one or more estrogen(s) dissolved at a total concentration of at least 40 mg per gram.

Claim 166 *(Previously presented)* The compounding method of claim 165, wherein said estrogen(s) are selected from estriol, estradiol, and estrone.

Claim 167 *CANCELLED*

Claim 168 *(Currently amended)* The compounding method of ~~claim 160~~ claim 164, wherein at least one of the concentrated reagent compositions contains at least one androgen at a concentration of at least 150 mg per gram.

Claim 169 *(Previously presented)* The compounding method of claim 168, wherein said androgen is selected from testosterone and dehydroepiandrosterone (DHEA).

Claim 170 *(Currently amended)* The compounding method of ~~claim 160~~ claim 164, wherein at least one of the concentrated reagent compositions contains at least one progestagen at a concentration of at least 200 mg per gram.

- Claim 171 *(Previously presented)* The compounding method of claim 170, wherein said progestagen is selected from progesterone and pregnenolone.
- Claim 172 *(Currently amended)* The compounding method of ~~claim 160~~ claim 164, comprising combining a plurality of concentrated reagent compositions, each containing a different estrogen.
- Claim 173 *(Currently amended)* The compounding method of ~~claim 160~~ claim 164, whereby the pharmaceutical product produced contains estriol and estradiol.
- Claim 174 *(Previously presented)* The compounding method of claim 173, wherein the ratio of estriol:estradiol by weight in the final product is 5:5, 6:4, 7:3, 8:2, or 9:1.
- Claim 175 *(Currently amended)* The compounding method of ~~claim 160~~ claim 164, whereby the pharmaceutical product produced contains estriol, estradiol, and estrone.
- Claim 176 *(Previously presented)* The compounding method of claim 175, wherein the ratio of estriol, estradiol, and estrone by weight in the final product is 8:1:1, 5:4:1, 6:3:1, or 7:2:1.
- Claim 177 *(Currently amended)* The compounding method of ~~any of claims 160-176~~ claim 164, in which one or more of said concentrated reagent composition(s) is color coded, and the method further comprises verifying the identity of the hormone(s) in the product according to the color of the pharmaceutical product after compounding.
- Claim 178 *(Currently amended)* The compounding method of ~~any of claims 160-176~~ claim 164, in which one or more of said concentrated reagent composition(s) is color coded, and the method further comprises verifying that the ingredients of the product have been adequately mixed according to whether the final product is a uniform color throughout.

Serial No. 10/668,075
Docket No. 025357.001
Page 7

Claims 179 to 184 *CANCELLED*